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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/732,783 | 12/10/2003 | David M. Hone | 4115-122 DIV 2 | 6909 |

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INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
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| EXAMINER | |
|---|---|
| WANG, LOUISE Z | |
| **ART UNIT** | **PAPER NUMBER** |
| 1648 | |

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/732,783 | HONE ET AL. | |
| | Examiner | Art Unit | |
| | Louise Wang | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-62 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-62 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

It is noted that Claim 45 recites the limitation "pharmaceutical composition" in Claim 37. There is insufficient antecedent basis for this limitation in the claim. For restriction purposes, Claim 45 is presume to depend on Claim 38. Correction is required.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, and 61, in part, drawn to a method of prevention or treatment of HIV infection comprising administering a chemokine, an anti-viral drug, and a lipolipopolysaccharide (LPS) variant, classified in class 424, subclass 283.1.

II. Claims 8-13, and 62, in part, drawn to a method of making a lipolipopolysaccharide variant, classified in class 424, subclass 283.1.

III. Claims 1-7, 61, in part, 19, and 21, drawn to a method of prevention and treatment of HIV infection comprising administering a chemokine, an anti-viral drug, and a lipolipopolysaccharide derivative, classified in class 424, subclass 283.1.

IV. Claims 14-18, 20, and 22, drawn to a method of making a lipopolysaccharide derivative, classified in class 424, subclass 283.1.

V. Claims 1-7, and 61, in part, and 23-28, drawn to a method of prevention and treatment of HIV infection comprising administering a chemokine, an anti-viral drug, and a lipopolysaccharide analog, classified in class 424, subclass 283.1.

VI. Claim 29, in part, drawn to a method of prevention and treatment of HIV using the combination of a lipopolysaccharide analog and derivative, classified in class 424, subclass 283.1.

VII. Claim 29, in part, drawn to a method of prevention and treatment of HIV using the combination of a lipopolysaccharide analog and variant, classified in class 424, subclass 283.1.

VIII. Claim 29, in part, drawn to a method of prevention and treatment of HIV using the combination of a lipopolysaccharide derivative and variant, classified in class 424, subclass 283.1.

IX. Claims 30 and 31, drawn to a method of prevention and treatment of HIV using the combination of a lipopolysaccharide antagonist and a second structure containing lipopolysaccharide or lipid A, classified in class 424, subclass 283.1.

X. Claims 32-37, drawn to a method of assaying a preparation comprising a variant, derivative or analog of lipopolysaccharide or lipid A, classified in class 424, subclass 283.1.

XI. Claims 38-44, in part, and 45-54, drawn to a pharmaceutical composition comprising a variant of lipopolysaccharide or lipid A which stimulates β-chemokine secretion but not pyrogenic cytokine release, and a chemokine, classified in class 424, subclass 283.1.

XII. Claims 38-44, in part, and 55-57, drawn to a pharmaceutical composition comprising a derivative of lipopolysaccharide or lipid A which stimulates β-

chemokine secretion but not pyrogenic cytokine release, and a chemokine, classified in class 424, subclass 283.1.

XIII. Claims 38-44, in part, and 58-60, drawn to a pharmaceutical composition comprising an analog of lipopolysaccharide or lipid A which stimulates β-chemokine secretion but not pyrogenic cytokine release, and a chemokine, classified in class 424, subclass 283.1.

The inventions are distinct, each from the other because:

Inventions I-X are different methods with respect to starting materials, procedures, and end products. Inventions I, III, and V-IX are methods of treatment using different lipid compounds, whereas Inventions II, IV, and X are methods of making different lipid compounds. Therefore, each method is patentably distinct.

Inventions XI-XIII are different products. The claimed compositions comprise lipid compounds with different structures, chemical properties and modes of action; therefore each product is patentably distinct.

Inventions (XI-XIII) and (I, III, V) are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, HIV treatment can be practiced with DNA or peptide vaccines and aptamers. The LPS or lipid A compounds have been used in the treatment of Gram-negative bacteremia and septic shock.

These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Furthermore, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

***Species Election***

Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

For each Group, Applicant is required to select a specific compound with a specific chemical structure in addition to the following:

If Group I, III, V, or any of XI-XIII is elected, Applicant is required to select a specific chemokine, as exemplified in claims 4 and 48.

If Group I, III, or V is elected, Applicant is additionally required to select a specific antiviral drug, as exemplified in claims 6 and 7.

If any one of Group VI-IX is elected, Applicant is required to select a second compound with a specific chemical structure.

These species are distinct because their structures, physicochemical properties and modes of action are different.

If Group II is elected, Applicant is required to elect a specific gram negative bacterium, as exemplified in claims 11-13, as well as a specific mutational gene, as exemplified in claims 9, 10, 12, 49, and 52.

These microorganism species are different in cellular components, genetic materials, mechanisms of replication, and modes of infection. These gene species are distinct because their nucleic acid sequences, structures, and functions are different.

If Group IV is elected, Applicant is required to select a specific modification method as exemplified in claims 16-18, and 20.

These species are different methods with respect to substrates, enzymes or catalysts, chemical reactions, and end products.

If Group X is elected, Applicant is required to select a specific assaying method as exemplified by claims 34-37.

These method species are distinct for the same reason as the inventions above.

Furthermore, the examination of these species would require different searches in the scientific literature, which would not be coextensive. As such, it would be burdensome to search these Species together.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

***Conclusion***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Contact Information***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Louise Wang
July 27, 2005

JEFFREY STUCKER
PRIMARY EXAMINER